

## REMARKS

In the most recently received (final) Official Action, the Examiner has requested a new submission in full compliance with the requirements for patent applications containing amino acid sequences. In addition, the Examiner has rejected previously pending claims 3, 8 and 11 respectively under 35 U.S.C. 101 as being directed to non-statutory subject matter. Finally, the Examiner has rejected previously pending claims 1-8 and 11-13 respectively under 35 U.S.C. 112, second paragraph, as being indefinite in language for specifically stated reasons.

In response, applicants have amended the Specification text at page 29, lines 19-20; amended claims 1-4 and 12-13 respectively; retained previously pending claims 4-8 and 11 respectively in unaltered form; and have enclosed the requisite documentary and CRF submissions in full compliance with the sequence rules, 37 C.F.R. 1.821-1.825. By these amendments, enclosures, and the discussion presented hereinafter, applicants believe they have overcome and obviated each basis for rejection stated by the Examiner in the most recently received (final) Official Action mailed April 11<sup>th</sup>, 2003.

I. Applicants' Submission In Fulfillment Of  
37 C.F.R. 1.821-1.825

The Examiner has stated that applicants' previous documentary and CRF submissions have failed to include the amino acid sequence (EYFA) as found at Page 29, line 19 of the Specification text, and therefore have failed to comply with the standards for patent applications containing amino acid sequences, as required by 37 C.F.R. 1.821-1.825.

Applicants and their undersigned attorney, however, find the Examiner's stated view and position to be puzzling on a substantive basis.

If the Examiner takes the time and effort to read the descriptive substance of the text appearing at Page 29 of the Specification, it is abundantly clear that the text relates to the degree of variability and substitution permitted within the specific DNA base sequencing for the cytoplasmic domain of the syndecan-4 molecule [Page 29, lines 13-15]. The permitted changes, point mutations, block substitutions and the like for the syndecan-4 molecule is the substance of the descriptive text [Page 29, lines 15-18]. For this reason, the language explicitly states that "The last four amino acids (EFYA) cannot be changed or modified" [page 29, line 19].

It is also clear from the explicit wording of the Specification text that the last four amino acids (EFYA) are not themselves a separate or independent segment; do not exist alone as an isolated amino acid sequence; and have no bearing or relevance except as the terminal four

amino acids present within the cytoplasmic domain as such of the syndecan-4 molecule. Thus, for the Examiner to insist on an individual sequence identity number and an individual amino acid sequence listing for such a component moiety is strange, to say the least.

However, owing to the formal Requirement imposed by the Examiner in the April 11<sup>th</sup>, 2003 Official Action, applicants, via their undersigned attorney, have chosen to acquiesce to the Examiner's stated position. Accordingly, applicants have thus prepared another documentary and CRF submission in compliance with the sequence rules, 37 C.F.R. 1.821 - 1.825, which identifies the amino acid sequence (EYFA) on Page 29, line 19 as "SEQ ID NO:25"; and the requisite documentary and CRF submissions are enclosed herewith in support of this Response.

For these reasons, applicants therefore respectfully request the Examiner to reconsider his stated position; and to withdraw this requirement against the Specification of the instant application.

## II.The Rejection Of Some Claims Under 35 U.S.C. 101

The Examiner has rejected previously pending claims 3, 8 and 11 under 35 U.S.C. 101 because the claimed invention is allegedly directed to non-statutory subject matter. Specifically, the Examiner believes that

scope for the these claims might encompass in vivo circumstances, which might encompass and include a living human being.

In response, applicants have amended the language of independent claim 3 to define the inventive subject matter as " An in-situ transfected endothelial cell which exists as part of a living tissue in vitro...". In this manner, the scope of amended independent claim 3 (and consequently also of dependent claims 8 and 11) is stated in precisely recited terms as an in-situ transfected cell to be found as part of a living tissue in vitro. Thus, by the explicit language in the preamble, the scope of claim 3 is controlled and limited to a in-vitro cell environment. This explicit wording thus cannot recite or identify an "in vivo" setting as such for the recited claim.

Accordingly, the subject matter recited by amended independent claim 3 (as well as of dependent claims 8 and 11 respectively) is deemed to be statutorily proper and correct. For these reasons, applicants respectfully request that the Examiner reconsider his position and withdraw this ground of rejection against the presently pending claims.

### III. The Rejection Under 35 U.S.C. 112, 2<sup>nd</sup> Paragraph

The Examiner has rejected previously pending claims 1-8 and 11-13 under 35 U.S.C. 112, 2<sup>nd</sup> paragraph as being vague and indefinite in

language. The Examiner's position is based on a range of wording problems in different claims.

In response, applicants have amended each of claims 1-3 and 12-13 respectively now pending. Applicants will address and summarize each specific question of language for these claims.

As regards independent claims 1-3 and 12-13, applicants have accepted the Examiner's offered suggestion and amended the language of these independent claims to recite -- a -- prior to "syndecan-4".

As regards independent claim 3 and the vagueness of the phrase "transfected endothelial cell which comprises a living tissue", applicants have amended the language to state -- transfected endothelial cell which exists as part of a living tissue --....

Finally, as regards the language of the pending claims as a whole, applicants note that the essential inquiry and legal requirement is to determine whether the language of the presently pending claims do set out and circumscribe a particular area or subject matter with a reasonable degree of precision and particularity. It is here where the meaning of the words and language employed to define the invention is analyzed; not in a vacuum, but always with regard to the teachings of the prior art and within the particular description, use or context disclosed by the Specification as it is understood and interpreted by one possessing

ordinary skill in the pertinent art [In re Angstadt, 190 U.S.P.Q. 214 (C.C.P.A. 1976)].

Applicants note that each of the terms used in presently pending claims 1-8 and 11-13 respectively is well understood; is not subject to numerous definitions and interpretations; and that there is no discrepancy, no confusion, and no ambiguity with regard to the antecedent descriptive basis and support provided by the Specification text. Rather, the language of the presently pending claims as a whole read on subject matter which is completely disclosed and enabled by the Specification text. Moreover, each recited element of the pending claims is explicit and clearly stated; and employs wording which sets forth and circumscribes the particular subject matter area with the requisite reasonable degree of precision and particularity [In re Moore, 169 U.S.P.Q. 236 (C.C.P.A. 1971)].


For these reasons, applicants respectfully submit that each and every claim now pending satisfies the requirements of precision, clarity, and particularity required by the second paragraph of 35 U.S.C. 112. Accordingly, applicants respectfully request that the Examiner reconsider his stated position and withdraw this ground of rejection against the presently pending claims.

*In sum*, applicants have addressed each basis of rejection stated in the instant Official Action forthrightly and objectively. In applicants' view, each issue or controversy has been evaluated, acted upon and resolved completely. For these reasons, applicants respectfully submit and affirm that presently pending claims 1-8 and 11-13 define patentable subject matter and are therefore now allowable.

In view of the above discussion and detailed review, applicants believe that this case is now in condition for allowance and reconsideration is respectfully requested. The Examiner is invited to call applicants' undersigned attorney should he feel that such a telephone call would further the prosecution of the present application.

Respectfully submitted,

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